

OVERVIEW OF AMENDMENTS & REMARKS

1. SPECIFICATION: No amendments.
2. CLAIMS STATUS:
  - a. No claims are allowed:
  - b. No canceled claims.
  - c. Amended (1) claim 6.
  - d. No new claims:
  - e. Total (4) patent claims pending:
    1. (3) independent claims: 1, 4 & 5.
    2. (1) dependent claims 6.
3. TRAVERSE OF REJECTION OF CLAIMS UNDER 35 USC SECTION 112 FIRST PARAGRAPH.
4. TRAVERSE OF REJECTION OF CLAIMS UNDER 35 USC SECTION 112 SECOND PARAGRAPH.
5. TRAVERSE OF REJECTION OF CLAIMS UNDER 35 USC SECTION 102.
6. TRAVERSE OF REJECTION OF CLAIMS 5 & 6 UNDER 35 USC SECTION 103(a).

Attachments: (items 7 & 8)

7. A PETITION FOR (1 MONTH) EXTENSION OF TIME (Rules 136(a) and 17(a)(1)) is enclosed with payment of fees (below).
8. FEE PAYMENT(S):
  - a. \$60.00 (check #977) - PETITION FOR (1 MONTH) EXTENTION OF TIME (above)
9. FEE STATUS: (small entity) A total of \$440 has now been paid on the present application per this AMENDMENT B which now presents (3) independent claims, and (1) dependent claim for a total of (4) claims.

BASIC NATIONAL FEE	\$440
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10. REQUEST FOR CONSTRUCTIVE ASSISTANCE

Applicant has made diligent effort to write the claims of this application in allowable condition. If for any reason the claims are not believed to be in full condition for allowance, Applicant respectfully requests the constructive assistance of Examiner pursuant to MPEP 707.07(j), and 706.03(d) in order that this application be placed in allowable condition as soon as possible.

REMARKS

11. **Claim 6 was amended**, Applicant submits that all the claims 1, & 4 - 6 are patentable.

AMENDMENTS TO CLAIMS

I claim:

1. **(Original)** A method of treating infectious diseases caused by drug-resistant strains of bacteria in a human or an animal host comprising:  
Administration to the area of disease a suitable carrier containing an antibacterial agent obtainable from pepper, or an equivalent in a therapeutically effective concentration.
2. **(Withdrawn)** A method of treating superficial bacterial infections in a human or an animal host comprising:  
Administration to the area of disease a suitable carrier containing an antibacterial agent obtainable from pepper, or an equivalent in a therapeutically effective concentration.
3. **(Withdrawn)** A method of treating internal bacterial infections in a human or an animal host comprising:  
Administration to the area of disease a suitable carrier containing an antibacterial agent obtainable from pepper, or an equivalent in a therapeutically effective concentration.
4. **(Previously presented)** A method of treating bacterial infections in a human or an animal host comprising:  
Administration to the area of disease a suitable carrier containing an antibacterial phytoalexin obtainable from pepper, or an equivalent in a therapeutically effective concentration.
5. **(Previously presented)** A method of treating cellulitis in a human or an animal host comprising:  
Administration to the area of disease a suitable carrier containing an antibacterial agent obtainable from pepper, or an equivalent in a therapeutically effective concentration.
6. **(Currently amended, 1<sup>st</sup> time)** The method of claim 5, wherein the disease [includes] is necrotizing fasciitis (flesh eating disease).

3. TRAVERSE OF REJECTION OF CLAIMS UNDER 35 USC SECTION 112 FIRST PARAGRAPH.

Claims 1 & 4-6 were rejected as not enabling a person skilled in the art to make and use the invention.

This rejection is traversed.

The patent specification is explicit as to specific formulations used in actual case studies.

A person skilled in the art is thereby enabled to both produce, and apply any of the formulations toward the treatment of diseases as specifically described, or to those related.

Beginning with production of a crude extract of pepper; a very simple, quick, and inexpensive procedure, a practitioner is at once well equipped with a remarkably effective medical treatment that is broad-spectrum in nature. From there, a practitioner has the further option of isolation or refinement of chemical components of the extract in order to optimize use toward more specific conditions, if so desired.

4. TRAVERSE OF REJECTION OF CLAIMS UNDER 35 USC SECTION 112 SECOND PARAGRAPH.

Claim 6 was rejected for failing to particularly point out, and distinctly claim the subject matter which applicant regards as the invention with use of the term “includes” which renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention.

This rejection is avoided by amendment of the claim.

Claim 6 was amended by replacement of the word “includes” with “is”.

Therefore this rejection should be withdrawn.

5. TRAVERSE OF REJECTION OF CLAIMS 1 & 4 UNDER 35 USC SECTION 102

Claims 1 and 4 were rejected as being anticipated by Yamaguchi et. al. who taught that piperine, an extract of black pepper showed activity against 2 strains of bacteria *Pseudomonas aeruginosa* and *Alcaligenes F2518*.

This rejection is traversed.

*Alcaligenes F2518* is not a pathogenic strain of bacteria, and thus does not apply to medical treatment of disease.

Therefore this rejection should be withdrawn.

*Pseudomonas aeruginosa* is only occasionally pathogenic to man and animals. The strain tested by Yamaguchi et. al. appears to be ordinary, and not associated with antibiotic drug resistance as in claim 1.

Claim 1 is distinct from this reference, in that it targets antibiotic drug-resistant strains of bacteria.

Therefore this rejection should be withdrawn.

Neither do Dorman et. al., make suggestion to use volatile oils of black pepper against antibiotic drug-resistant strains of bacteria.

The claim 4 “phytoalexins” are distinct from piperine and volatile oils of black pepper found in the cited references.

Therefore this rejection should also be withdrawn.

The invention as claimed is therefore novel, as the cited references fail to identify all elements of the invention as claimed, and should be withdrawn.

**6. TRAVERSE OF REJECTION OF CLAIMS 5 & 6 UNDER 35 USC SECTION 103(a).**

Claims 5 & 6 were rejected on Examiner assertion that one skilled in the art (in view of Yamaguchi et. al., Dorman et. al. cited references) would have assumed that the administration of piperine or volatile oils of black pepper would be effective to treat cellulites infection commonly caused by staph, strep, and other bacteria.

This rejection is traversed.

The cited references show *in vitro* screens of bacteria vs. piperine or volatile oils of black pepper.

Those skilled in the art also recognize that an *in vitro* display of antimicrobial activity, though evidential, is not in itself a certainty that the compound would function effectively as a medical treatment. If this were true, a mere soap and water washing of an infected area resulting in the killing a number of bacteria would assure rapid cure. Effective treatment of infectious disease is far more complex than simply killing a portion of the pathogenic bacteria at the site of infection.

Many thousands of compounds have shown antibiotic activity *in vitro*, yet effective antibiotic drugs are relatively few in number.

A medical treatment for cellulitis, derived from pepper is not suggested in these references, or in the prior art as a whole.

In particular with a disorder such as cellulitis, which effects deeper levels of tissue below skin level, and involves issues regarding drug delivery and bio-availability ect. in order to reach site of infection. The present invention addresses these issues of delivery to the site of infection in addition to direct biocidal effect.

The above factors are disclosed in the present invention, and not found among the cited references.

This rejection as to obviousness is not proper and should be withdrawn.

Nothing further at this time.

Respectfully,

  
10/3/05  
Jeff J. Staggs,  
Applicant

The following received today

Item	# of Sheets
1. <u>Amendment B</u> signed and dated 10/03/05 with a Certificate of Mailing signed and dated 10/03/05.	8
2. <u>Petition for (1 month) Extension of Time Form PTO/SB/22 (12-04).</u>	1
3. <u>Check (#977) for \$60 for Petition fee 37 CFR 1.17(a)(1).</u>	1
4. <u>This self-addressed stamped return post card:</u>	1
<b>TOTAL</b>	<b>11</b>

Serial Number : 10/620/794

Filing Date : 15 July 2003

Applicant : Jeff J. Staggs, 9381 Princeton Ln., Highlands Ranch CO 80130

Appn. Title : "Treatment for Bacterial Infections and Related Disorders"

Certificate of Mailing

I certify that this correspondence entitled Amendment B will be deposited with the United States Postal Service as first class mail with proper postage affixed in an envelope addressed to: Commissioner for Patents, P.O. Box 1450 Alexandria VA 22313-1450 on October 3, 2005.

  
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Jeff J. Staggs, Applicant

10/3/05  
Date